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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/118,730	07/17/1998	ELLINGTON M. BEAVERS	:281-28	9320

7590

01/22/2004

WILLIAM H EILBERG
420 OLD YORK ROAD
JENKINTOWN, PA 19046

EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 01/22/2004

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/118,730

Applicant(s)

BEAVERS ET AL.

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 20-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Pursuant to the Remand by the Board of Patent Appeals and Interferences on February 28, 2002, prosecution is hereby reopened. A new ground of rejection is set forth below.
2. Claims 1-8 and 20-23 are pending in the case.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

4. Claims 2-8 and 21-23 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 2-8 and 21-23 only set forth process limitations and are of improper dependent form since independent Claims 1 and 20 are directed to a product. Applicants are reminded that the Office considers product-by-process claims as product claims. Process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art. *In re Thorpe et al.* (CAFC 1985), *supra*; *In re Dike* (CCPA 1968) 394 F2d 584, 157 USPQ 581; *Tri-Wall Containers, Inc. v. United States et al.* (Ct Cls 1969) 408 F2d 748, 161 USPQ 116; *In re Brown et al.* (CCPA 1972) 450 F2d 531, 173 USPQ 685; *Ex parte Edwards et al.* (BPAI 1986) 231 USPQ 981.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-8 and 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by The Merck Index, 12th Edition, 1996, Abstract No. 4793, pages 813 and 814 (already of record).

Applicants claim a free-acid form of hyaluronic acid in the form of product-by-process claims in Claims 1 and 20 and additional limitations in the dependent claims (see Claims 2-8 and 21-23) only set forth process limitations. Applicants are reminded that process limitations cannot impart patentability to a product, which is not patentably distinguished over the prior art. *In re Thorpe et al.* (CAFC 1985), *supra*; *In re Dike* (CCPA 1968) 394 F2d 584, 157 USPQ 581; *Tri-Wall Containers, Inc. v. United States et al.* (Ct Cls 1969) 408 F2d 748, 161 USPQ 116; *In re Brown et al.* (CCPA 1972) 450 F2d 531, 173 USPQ 685; *Ex parte Edwards et al.* (BPAI 1986) 231 USPQ 981.

The Merck Index shows that hyaluronic acid is well known in the art (see Abstract No. 4793, pages 813 and 814). The Merck Index characterizes hyaluronic acid as having: a molecular weight within the range of 50,000 to 8×10^6 depending on source, methods of preparation and determination; a natural high viscosity mucopolysaccharide with alternating (1-3) glucuronic and (1-4) glucosaminidic bonds (see the structure hyaluronic acid on page 813 of the Merck Index which is in the free-acid form); found in the umbilical cord, in vitreous humor, in synovial fluid, in pathologic joints, in group A and C hemolytic streptococci and in Wharton's jelly; used as a surgical aid (ophthalmological) and adjunct in the treatment of noninfectious synovitis. While Applicants's claims are directed to a product limited by the process employed in its production there is no reason found for concluding that the product claimed (e.g., free acid form of hyaluronic acid) could be distinguished from the free acid form of hyaluronic acid of the Merck Index merely because the claimed product was produced under the specific conditions recited, which conditions fall within the purview of the disclosure of the Merck Index. Accordingly, the free-acid form of hyaluronic acid set forth in the Merck Index anticipates the instantly claimed free-acid form of hyaluronic acid.

7. Claims 1-8 and 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Meyer (Fed. Proc., "Chemical Structure of Hyaluronic Acid", Vol. 17, (December 1958) pages 1075-1077, newly added).

Applicants claim a free-acid form of hyaluronic acid in the form of product-by-process claims in Claims 1 and 20 and additional limitations in the dependent claims (see Claims 2-8 and 21-23) only set forth process limitations. Applicants are reminded that process limitations cannot impart patentability to a product, which is not patentably distinguished over the prior art. *In re Thorpe et al.* (CAFC 1985), *supra*; *In re Dike* (CCPA 1968) 394 F2d 584, 157 USPQ 581; *Tri-Wall Containers, Inc. v. United States et al.* (Ct Cls 1969) 408 F2d 748, 161 USPQ 116; *In re Brown et al.* (CCPA 1972) 450 F2d 531, 173 USPQ 685; *Ex parte Edwards et al.* (BPAI 1986) 231 USPQ 981.

The Meyer reference establishes the chemical structure of hyaluronic acid, which is demonstrated in Fig. 1, Fig. 2 and Fig. 3. See Fig. 3 of the Meyer reference, which sets forth a detail chemical structure of hyaluronic acid in free-acid form, which anticipates the free-acid form of hyaluronic acid set forth in the instant claims.

8. The following references are cited to further show the state of the art:

Meyer et al, "The Polysaccharide of the Vitreous Humor", Journal of Biol. Chem., Vol. 107, (1934) pages 629-634, mentioned the free acid form of hyaluronic acid being very hygroscopic;

Laurent et al, "Fractionation of Hyaluronic Acid and Polydispersity of Hyaluronic Acid from the Bovine Vitreous Body" Biochim. Biophys. Acta, Vol. 42 (1960) pages 476-485;

Peyron et al, "Preliminary Clinical Assessment of NaHyaluronate Injection Into Human Arthritic Joints", Vol. 22, No. 8, Oct. 1974, pages 731-736;

Rydell, "Decreased Granulation Tissue Reaction after Installment of Hyaluronic Acid", Acta Orthop. Scandinav., Vol. 41, 1970, pages 307-311;

Rydell, "Effect of Intra-Articular Injection of Hyaluronic Acid on Clinical Symptoms", Clinical Orthopaedics, Oct. 1971, No. 80, pages 25-32; and

Balazs, US Patent No. 4,141,973, discloses ultrapure hyaluronic acid and use thereof.

Summary

9. All the pending claims (Claims 1-8 and 20-23) are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

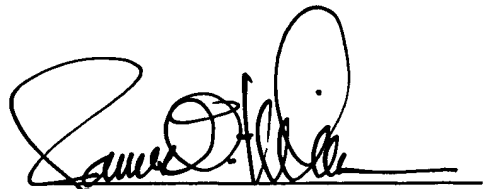
10. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


E. White


James O. Wilson
Supervisory Primary Examiner
Technology Center 1600